

### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Rick Matos on 02/04/2209.

The application has been amended as follows:

In claim 5, line 1, after "claim" delete "4" and insert --- 48 --- and after "containing" insert --- water soluble and/or erodible external ---

In claim 41, line 1, after "claim" delete "1" and insert --- 48 ---

In claim 43, line 1, after "claim" delete "4" and insert --- 48 ---

In claim 44, line 1, after "claim" delete "1" and insert --- 48 ---

In claim 48, line 4, after "semipermeable" delete "membrane" and insert ---coat --- and line 5, after "and" insert --- an inert water soluble and/or erodible coat disposed between the semipermeable membrane and the drug-containing coat : and ---

In claim 48 at the very end of the table insert a period --- .---

Cancel claims 1, 4, 13-20, 32-40 and 53-57.

### **ALLOWABLE SUBJECT MATTER**

1. Claims 5, 41, 43-44 and 48-52 are allowed.
2. The following is an examiner's statement of reasons for allowance: The closest prior art was that which is cited in the previous office action filed on 09/05/2008,

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especially Wong et al (US 4,783,337) and Faour (US 6,352,721) in view Savastano et al (US 5,681,584) and Smolka et al (WO 2003/097041 A1). The combination of Wong, Faour and Savastano patents teaches most essential elements of the invention, but fails to teach specifically the use of pharmaceutically active substance licofelone and pharmaceutically acceptable ingredients in specific amounts that produces local or systemic effect in human and primates as recited in claim 48. The claimed subject matter is not taught or suggested by the cited reference and thus, the claimed subject matter is considered to be novel and patentably distinct over the prior art of the record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

Jagadishwar R Samala  
Examiner  
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sjr